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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/758,761

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EXAMINER

HANDY, DWAYNE K

ART UNIT

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1797

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/758,761	Applicant(s) LEWIS ET AL.	
	Examiner DWAYNE K. HANDY	Art Unit 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 November 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 24,25,27-30 and 32-42 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 24,25,27-30 and 32-42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 37-40 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the bypass valve, carrier gas source, vaporizing chamber, and sensor array, does not reasonably provide enablement for the fluid concentrator. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims. As noted in Paragraphs 1 and 2 of the previous Office Action (mailed 8/21/07), the embodiments of Applicant's disclosed devices that include the fluid concentrator are shown in Figures 1-3. Figures 1 and 2 show the breath collector and concentrator (BCC) while Figure 3 shows the head space analyzer (HAS). The BCC is adapted to collect breath samples from various locations (Specification, page 6, line 16 – page 7, line 10). These devices are not the anesthetic vapor system shown in Figure 4 and described on pages 19 and 20 of the Specification. Applicant has not described use of a fluid concentrator with the anesthetic system nor shown this element in Figure 4 other than to state that "a fluid concentrator is optionally used when monitoring and quantitating anesthetic concentration". This disclosure is insufficient to enable claims 37-40 as currently written.

Inventorship

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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5. Claims 24, 25, 27-30, 32-36, 41 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rusz (5,546,931) in view of Lewis et al. (5,571,401). This rejection was applied to claims 24, 25, 27-36, 41 and 42 in the Office Action mailed 3/21/07. It is reinstated in response to Applicant's amendment submitted 11/16/07. Rusz teaches an anesthetic vapor delivery apparatus. The apparatus is shown in Figure 1. The apparatus includes a carrier gas source (11), a bypass valve (17), a vaporizing chamber (26) controlled through temperature and pressure sensors, a conduit from the vaporizer, and an anesthetic concentration sensor disposed downstream of the joining port (19). Rusz does not teach an array of sensors disposed downstream of the joining port. Lewis teaches a sensor array. The array is comprised of a plurality of conductive polymer sensors having a different response to an analyte. The device is best described in columns 6 and 7:

In operation, each resistor provides a first electrical resistance between its conductive leads when the resistor is contacted with a first fluid comprising a chemical analyte at a first concentration, and a second electrical resistance between its conductive leads when the resistor is contacted with a second fluid comprising the same chemical analyte at a second different concentration. The fluids may be liquid or gaseous in nature. The first and second fluids may reflect samples from two different environments, a change in the concentration of an analyte in a fluid sampled at two time points, a sample and a negative control, etc. The sensor array necessarily comprises sensors which respond differently to a change in an analyte concentration, i.e. the difference between the first and second electrical resistance of one sensor is different from the difference between the first second electrical resistance of another sensor.

In a preferred embodiment, the temporal response of each sensor (resistance as a function of time) is recorded. The temporal response of each sensor may be normalized to a maximum percent increase and percent decrease in resistance which produces a response pattern associated with the exposure of the analyte. By iterative profiling of known analytes, a structure-function database correlating analytes and response profiles is generated. Unknown analyte may then be characterized or identified using response pattern comparison and recognition algorithms. **Accordingly, analyte detection systems comprising sensor arrays, an electrical measuring device for detecting resistance across each chemiresistor, a**

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computer, a data structure of sensor array response profiles, and a comparison algorithm are provided. In another embodiment, the electrical measuring device is an integrated circuit comprising neural network-based hardware and a digital-analog converter (DAC) multiplexed to each sensor, or a plurality of DACs, each connected to different sensor(s).

A wide variety of analytes and fluids may be analyzed by the disclosed sensors, arrays and noses so long as the subject analyte is capable generating a differential response across a plurality of sensors of the array. Analyte applications include broad ranges of chemical classes such as organics such as alkanes, alkenes, alkynes, dienes, alicyclic hydrocarbons, arenes, alcohols, ethers, ketones, aldehydes, carbonyls, carbanions, polynuclear aromatics and derivatives of such organics, e.g. halide derivatives, etc., biomolecules such as sugars, isoprenes and isoprenoids, fatty acids and derivatives, etc. **Accordingly, commercial applications of the sensors, arrays and noses include environmental toxicology and remediation, biomedicine, materials quality control, food and agricultural products monitoring, etc.**

The general method for using the disclosed sensors, arrays and electronic noses, for detecting the presence of an analyte in a fluid involves resistively sensing the presence of an analyte in a fluid with a chemical sensor comprising first and second conductive leads electrically coupled to and separated by a chemically sensitive resistor as described above by measuring a first resistance between the conductive leads when the resistor is contacted with a first fluid comprising an analyte at a first concentration and a second different resistance when the resistor is contacted with a second fluid comprising the analyte at a second different concentration.

It would have been obvious to one of ordinary skill in the art, then, to combine the sensor array from Lewis with the device of Rusz. Rusz uses a single oxygen sensor in combination with a temperature and pressure sensor in combination to determine the concentration of the anesthetic. One would add the sensor array from Lewis to allow for the direct measurement of the anesthetic as well as other components of the fluid stream. This would improve the quality of the control mechanism as suggested by Lewis.

6. Claims 37-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rusz (5,546,931) and Lewis et al. (5,571,401) in view of Georgieff et al. (5,520,169).

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This rejection was applied to claims 26 and 37-40 in the Office Action mailed 3/21/07. It is reinstated in response to Applicant's amendment submitted 11/16/07. Rusz and Lewis teach every element of claims 37-40 except for the absorbent element and method step of vapor concentration with the absorbent. Georgieff teaches an anesthesia system. The system includes a purification unit (9) on the anesthesia transport line (8) for purifying the gas in the line. The purification unit is described in column 4, line 62 – column 5, line 7. It includes a molecular sieve for trapping gasses. It would have been obvious to one of ordinary skill in the art to combine the purification unit/step from Georgieff with the system of Rusz. One would add the molecular sieve purification unit from Georgieff to remove any unwanted gases from the anesthetic stream.

Response to Arguments

7. Applicant's arguments filed 11/16/07 have been fully considered but they are not persuasive. Applicant has amended claim 24 to recite the limitation of "wherein the anesthetic is injected directly into the carrier gas stream". Applicant has then argued that Rusz does not teach this feature. The Examiner respectfully disagrees and notes that Applicant appears to be arguing that this limitation conveys or requires some form of injection element. This argument is beyond the scope of the claim. Applicant has not provided any disclosure of an injection element in the Specification. Given its broadest reading, then, the term "inject" merely means "to force a fluid into something". The Examiner submits that the port (19) of Rusz serves this function; anesthetic flows from

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the vaporization chamber (26) via the outlet port (28) to a pump (30) where it is forced through the port (19) and into the carrier gas stream flowing in the carrier gas conduit (12).

8. Applicant has also argued that Rusz does not teach a breath collector concentrator. The Examiner agrees that Rusz does not provide this element. This feature is provided by the Georgieff reference. The Examiner has provided a rejection under Rusz, Lewis et al., and Georgieff et al. in Paragraph 6 above. In addition, the Examiner again notes that the claims that include this feature also remain rejected under USC 112, 1st Paragraph.

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to DWAYNE K. HANDY whose telephone number is (571)272-1259. The examiner can normally be reached on M-F 8:00-4:30.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571)-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

DKH
February 4, 2008


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